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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/241,455	02/02/99	KRIVITSKI	N	20850/40006

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EXAMINER	
SZMAL, B	
ART UNIT	**PAPER NUMBER**
3736	3

DATE MAILED: 10/19/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/241,455	Krivitski
Examiner	**Group Art Unit**
Brian Szmal	3736

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-29 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Comments

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 19, 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al.

Williams et al discloses a device for thermodilution by heat exchange through a catheter wherein claims 19, 20 and 22-24 are discussed in Column 4 and seen in Figure 1. The equation for blood flow is described in Column 7, lines 21-4.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al in view of Salo et al.

Williams et al, as discussed above, discloses a device and method for thermodilution by heat exchange through a catheter wherein the blood flow is determined in response to an altered blood property past the sensor (see Column 13, lines 34-45); and locating a plurality of blood parameter sensors in the vessel (see Column 13, lines 34-45).

Williams et al however does not disclose the method of locating a blood parameter altering section in the vessel, performing a stenosis reduction procedure, and the stenosis reduction procedure includes angioplasty.

Salo et al discloses a dimension sensitive angioplasty catheter method wherein a blood parameter altering section is located (see Column 9, lines 11-23); performing a stenosis reduction procedure (see Column 9, lines 17-23); and the stenosis reduction procedure includes angioplasty (see Column 9, lines 24-28).

Since both Williams et al and Salo et al disclose the use of a catheter for determining the blood flow rate in a vessel, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Williams et al to include the method of locating a blood parameter altering section and performing angioplasty as a stenosis reduction procedure , as per the teachings of Salo et al in order to allow the cardiologist to determine if the angioplasty was successful in increasing the blood flow rate, and if it was not, perform another balloon inflation to ensure increased blood flow rate. It also would have been obvious to have the blood parameter section downstream from the altering section to allow the cardiologist to determine with ease whether or not the first angioplasty inflation was successful. It also would have been

obvious to locate the blood parameter sensor in order to reduce the wall effects from the vessel so the sensors would not be impeded during the procedure thus giving false information. It also would have been obvious to rotate the blood parameter sensors with respect to the vessel to reduce wall effects from the vessel in order to permit proper blood flow to the sensors during the procedure.

5. Claims 1-7 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant in view of Tanabe et al.

Bryant discloses a blood flow measuring method wherein the apparatus includes an elongate catheter having a angioplasty balloon (see Column 2, lines 64-6); the sensors are located with respect to the vessel to minimize wall effects (see Column 3, lines 43-53); a controller connected to the sensor to calculate flow rate (see Column 3, lines 14-7 and 34-7); the signal from the sensor corresponds to the blood flow in the vessel (see Column 3, lines 48-53); and a stenosis reducing member actuatable to reduce stenosis in the vessel (see Column 3, lines 43-45). Bryant however does not disclose the use of a blood property change port and a downstream sensor, the blood property change port includes an aperture for introducing a blood property variant, the blood property change port and the sensor are spaced by a sufficient distance, the blood property change port includes one of a heat sink and a heat source for creating a local temperature gradient, a dilution indicator source, and a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to a signal from the sensor.

Tanabe et al discloses a catheter for determining blood flow wherein there is a blood property change port and a downstream sensor (see Column 4, lines 17-38); the blood property includes an aperture for introducing a blood property variant (see Column 4, lines 55-7); the blood property change port includes one of a heat sink and a heat source for creating a local temperature gradient (see Column 4, lines 61-4); a dilution indicator source (see Column 4, line 68); and a controller connected to the dilution indicator source and the sensor for calculating the blood flow (see Column 14, lines 49-58).

Since both Bryant and Tanabe et al disclose blood measurement catheters, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Bryant to include a blood property change port having an aperture, a heat sink and a heat source, a dilution indicator source, and a controller connected to the dilution indicator source and the sensor for calculating the blood flow, as per the teachings of Tanabe et al, in order to allow the cardiologist to determine with accuracy the blood flow rate through a vessel. It also would have been obvious to combine an angioplasty catheter with that of a blood flow calculating catheter. It also would have been obvious to use the balloon in the invention of Bryant to open blood vessels as an angioplasty balloon does. It also would have been obvious to use the invention of Tanabe et al with an angioplasty procedure.

6. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant and Tanabe et al in view of Williams et al.

Bryant discloses a blood flow measuring catheter wherein there is an expanding angioplasty balloon (see Figure 1).

Bryant fails to disclose inserting the catheter and a blood property sensor into a vessel, introducing a first change in the blood property upstream of the blood property sensor, and detecting passage of the first change in the blood property upstream of the sensor.

Tanabe discloses a catheter for measuring blood flow wherein the catheter is inserted and a blood property sensor is inserted (see Column 6, lines 59-68 and Column 7, lines 1-6); introducing a first change in the blood property upstream of the blood sensor (see Column 5, lines 50-8); and detecting passage of the first change in the blood property upstream of the sensor (see Column 4, lines 35-8).

Bryant and Tanabe et al however fail to disclose detecting a second change in the blood property, determining the change in flow from the first change and second change in the blood property, and inserting a catheter and a blood property sensor into a vessel having a blood flow corresponding to the angioplasty.

Williams et al discloses a thermodilution catheter wherein there is a second detection of a change in blood property (see Column 13, lines 14-23); determining the change in flow (see Column 13, lines 24-7); and inserting a catheter and a blood property sensor into a vessel (see Abstract).

Since Bryant, Tanabe et al and Williams et al all disclose methods and devices for measuring blood flow rates in vessels, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the devices of Bryant and Tanabe et al to include

detecting a second change in blood property and determining the change in flow from the first and second trials, as per the teachings of Williams et al, in order to allow the cardiologist to find the most accurate figures from blood flow following the procedure. It also would have been obvious to have the measurements take place following an angioplasty procedure to attain an accurate blood flow rate. It also would have been obvious to have a second change in the blood property to allow an average of values in the flow rate to be more accurate rather than risk having the possibility the first measurement was erroneous. It also would have been obvious to have a first catheter having the angioplasty balloon and a second catheter having the blood sensor to create a component system that would allow a cardiologist the option of using one or the other or both at the same time.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant and Tanabe et al as applied to claims 1-7 above, and further in view of Williams et al.

Bryant and Tanabe et al disclose blood flow measurement catheters but fail to disclose the equation for determining the blood flow.

Williams et al discloses the use of thermodilution by catheter wherein the area under the temperature-time curve is inversely proportional to the cardiac output (see Column 7, lines 21-4). Since Bryant, Tanabe et al and Williams et al all describe means for determining blood flow in a vessel, it would have been obvious to ne of ordinary skill in the art at the time the invention was made to modify the devices of Bryant and Tanabe et al to include the use of the equation for determining blood flow, as per the teachings of Williams et al, in order to mathematically

determine the blood flow in the vessel. It also would have been obvious to use the inverse proportionality of the area under the temperature-time curve in the place of the area under the dilution curve to determine the mathematic value of the blood flow in the vessel.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758.

Max Hindenburg
Primary Examiner

BS

October 15, 1999